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EXAMINER

KUMAR, VINOD

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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,199	Applicant(s) LIGHTNER ET AL.	
	Examiner VINOD KUMAR	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-9 and 14 in the reply filed on May 20, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-15 are pending.

Claims 10-13 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Accordingly, claims 1-9 and 14 are examined on merits in the present Office action.

This restriction is made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. Initialed and dated copy of Applicant's IDS form 1449 filed in the paper of February 2, 2007 is attached to the instant Office action. The submission is in

compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

3. The listing of references in the specification (pages 31-32) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

4. Claims 1 and 6 are objected to because of the following informalities:

Claims 1 and 6 are objected for reciting "control plants". It is suggested to replace "control plants" with --an untransformed plant of the same species--.

Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in their recitation "or an ortholog thereof" with regard to SEQ ID NO: 2. The

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specification at page 11, lines 3-4 of paragraph 0037 states that orthologs of HIO32.2 as genes from other species that retain the same function due to the presence of one or more protein motifs and/or 3-dimensional structures. Also see the specification at paragraph bridging pages 7 and 8, wherein the specification states that an ortholog of HIO32.2 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity or cellular or extra-cellular localizing activity. However, the list of possible functional activities is open ended, and most of the activities listed are generic, such as catalytic activity, binding activity, and signaling activity, wherein these functional activities are found in many divergent polypeptides that are not associated with producing a high oil phenotype in a plant. In addition, the specification does not set forth any protein motifs or 3-dimensional structure that would identify an ortholog of HIO32.2. Thus, the use of "ortholog" in the claim does not set forth the metes and bounds of the claimed invention.

Dependent claims 2-5, 7-9 and 14 are also rejected because they fail to overcome the deficiency of claims 1 and 6.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "an altered oil content phenotype" in part b) which is confusing since preamble says "a method of producing a high oil phenotype in a plant", whereas the last method step results in an altered (increase/decrease) in oil content. It is unclear what is intended.

Claims 7 and 8 are also rejected because they fail to overcome the deficiency of claim 6.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "a plant that is the direct progeny", which is confusing, since it is unclear whether the plant obtained from the direct progeny comprises the nucleotide sequence.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "a plant that is the indirect progeny", which is confusing, since it is unclear whether the plant obtained from the indirect progeny comprises the nucleotide sequence.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "direct progeny" in line 2, and "indirect progeny" in line 3, which is confusing since it is unclear which "direct progeny" or "indirect progeny" is being referred to. It is also unclear how a "direct progeny" is different from an "indirect progeny". It is unclear what is intended.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a transgenic plant and a method of making said transgenic plant comprising a nucleic acid sequence that encodes a HIO32.2

polypeptide as set forth in SEQ ID NO: 2, does not reasonably provide enablement for (i) a transgenic plant with increased oil content or a method of producing said transgenic plant comprising a nucleotide sequence that encodes an ortholog of SEQ ID NO: 2 and (ii) a transgenic plant with increased oil content or a method of making said transgenic plant comprising a nucleotide sequence which is complementary to a nucleotide sequence that encodes SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claims are broadly drawn to a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO32.2 polypeptide comprising an amino acid sequence which is ortholog of SEQ ID NO: 2, whereby the transgenic plant has a high oil phenotype relative to a control plant, or a method of producing oil comprising growing said transgenic plant, and recovering oil from said plant, or a method of producing a

high oil phenotype in a plant comprising introducing into progenitor cells of the plant a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO32.2 polypeptide comprising an amino acid sequence which is ortholog of SEQ ID NO: 2, growing the transformed progenitor cells to produce a transgenic plant, wherein the polynucleotide sequence is expressed, and said transgenic plant exhibits an altered oil content phenotype relative to control plants.

Claims 1 and 6 are directed to a nucleotide sequence encoding an ortholog of SEQ ID NO: 2. It is important to note that Office is interpreting “an ortholog thereof” in claims 1 and 6 as ortholog of SEQ ID NO: 2.

The instant specification, however, only provides guidance for how to make and use a nucleotide sequence encoding the protein of SEQ ID NO: 2, in a method of producing a transgenic *Arabidopsis* plant and transgenic seeds derived thereof. The transgenic seeds exhibited increased oil content compared to non-transgenic control seeds. See in particular, pages 19-20, example 2; pages 26-30, example 5.

The instant specification fails to provide guidance on how to make nucleic acid sequences encoding orthologs of SEQ ID NO: 2 that have the property of increasing oil content when overexpressed in a transgenic plant.

The specification at page 11, paragraph 0037, lines 1-16, says:

Orthologs of the present invention encompass paralogs. Orthologs are generally identified by sequence homology analysis. Normally, orthologs in different species retain the same function, due to presence of one or more protein motifs and/or 3-dimensional structure.

The state of the art for inferring a structure function relationship based on sequence homology is highly unpredictable. The functional prediction of a protein

based on structural comparison is not consistent with an empirical assessment of its function. See for example, Doerks *et al.*, (TIG, 14:248-250, 1998) who teach that sequence homology is not sufficient to determine functionality of an uncharacterized protein. The homologs that scored best in PSI-BLAST analysis failed to share same catalytic activity. The reference clearly emphasizes that computer analysis of genome sequences is flawed, and overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions. See in particular, page 248, 1st paragraph; page 248, right column, 2nd paragraph.

Also see Smith et al. (Nature Biotechnology, 15:1222-1223, 1997) who teach that there are numerous cases in which proteins of very different functions are homologous. See in particular, page 1222, last paragraph.

Also see Bork et al. (TIG, 12:425-427, 1996) who teach that homology search methods are stretched and spurious hits are taken as real. The reference further teaches that similarities determined by homology search might only be restricted to certain domains of the uncharacterized protein, whereas the whole protein is required for the functionality of the protein. See page 426, right column, 1st paragraph.

The specification at paragraph bridging pages 7 and 8 says:

An ortholog of HIO32.2 would exhibit one or more of the functional activities associated with the polypeptide of SEQ ID NO: 2, which can include, but are not limited to: signaling activity, binding activity, catalytic activity.

However, the specification does not set forth how expression of the HIO32.2 polypeptide confers a high oil phenotype on a transformed plant. The specification states that the functional activity of HIO32.2 and orthologs thereof may be any of a signaling activity, a binding activity, a catalytic activity or a cellular or extra-cellular localizing activity. Yet none of these functional activities are demonstrated for SEQ ID NO: 2 or for any orthologs thereof, and the specification does not teach how to assay for any of these functional activities.

An ortholog of SEQ ID NO: 2 would encompass any protein having helix-loop-helix DNA-binding domain. An ortholog of SEQ ID NO: 2 would also encompass any bHLH transcription factor protein. The state of art also teaches that bHLH transcription factor are involved in activating stress-responsive genes. See for example, Smolen et al. (Genetics, 161:1235-1246, 2002; see in particular abstract)

An ortholog of SEQ ID NO: 2 would also encompass unspecified changes in the amino acid sequence of SEQ ID NO: 2.

The specification does not provide guidance in the specification with respect to making amino acid changes (substitutions, additions, deletions and/or insertions) in SEQ ID NO: 2.

Thus, from the guidance in the specification, it would appear that the vast majority of the amino acids in SEQ ID NO: 2 could be substituted with any other amino acid.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO: 2 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain the functional activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

Making amino acid substitutions in SEQ ID NO: 2 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see for example, Wells, *Biochemistry* 29:8509-8517, 1990, see pages 8511-8512, tables 1-2; Ngo et al., pp. 492-495, 1994, see page 491, 1st paragraph).

Also, see Guo et al. (*PNAS*, 101: 9205-9210, 2004, see page 9205, abstract; page 9206, table 1; page 9208, figure 1) who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as the claim encompasses more than a single amino acid changes in the encoded protein of SEQ ID NO: 2.

Also see, Keskin et al. (Protein Science, 13:1043-1055, 2004, see page 1043, abstract) who teach that proteins with similar structure may have different functions. Furthermore, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000, page 992, 2nd paragraph bridging columns 1 and 2) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions.

More specifically, identification of related sequences that will encode enzymes having a particular catalytic activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. In fact, Broun et al. (Science, 282:1315-1317, 1998) teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least).

Thus, making and analyzing proteins with large amino acid changes that have a biological activity would require undue experimentation.

Thus, making and analyzing proteins with large amino acid changes in SEQ ID NO: 2 that also have the activity of increasing oil content when overexpressed in a plant would require undue experimentation.

Thus, extensive teachings are required for making nucleic acids encoding a protein with unspecified amino acid substitutions relative to SEQ ID NO: 2, as encompassed by the claimed nucleic acids. These teachings are not provided for by the specification. The specification also fails to overcome the unpredictability of making large numbers of amino acid substitutions in SEQ ID NO: 2 protein as it provides no working examples of proteins with unspecified amino acid substitutions relative to SEQ ID NO: 2.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins having unspecified amino acid changes in SEQ ID NO: 2 that can be used in a method of obtaining a plant with higher oil content. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

Claims 1 and 6 are also directed to a nucleotide sequence which is complementary to a sequence that encodes SEQ ID NO: 2. This implies that said nucleotide sequence would either encode no polypeptide, or encode a polypeptide that may have 0% sequence identity to SEQ ID NO: 2. The specification provides no guidance on how to use said nucleotide sequences in obtaining transgenic plants with increased oil content. Claims 1 and 6 also read on antisense expression of a nucleic acid sequence which encodes SEQ ID NO: 2. The specification fails to provide

guidance how antisense expression of a nucleic acid sequence that encodes SEQ ID NO: 2 in a plant would result in increase in oil content.

In the absence of guidance, undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to determine how said complementary nucleic acid sequences could have been used to produce plants with increased oil content in a plant.

Thus in the absence of adequate guidance from the specification, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with increased oil content, if such plants are even obtainable.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention commensurate in scope with the claims.

7. Claims 1-9 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed

subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims are broadly drawn to a transgenic plant comprising a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a

sequence that encodes a HIO32.2 polypeptide comprising an amino acid sequence which is ortholog of SEQ ID NO: 2, whereby the transgenic plant has a high oil phenotype relative to a control plant, or a method of producing oil comprising growing said transgenic plant, and recovering oil from said plant, or a method of producing a high oil phenotype in a plant comprising introducing into progenitor cells of the plant a plant transformation vector comprising a nucleotide sequence that encodes or is complementary to a sequence that encodes a HIO32.2 polypeptide comprising an amino acid sequence which is ortholog of SEQ ID NO: 2, growing the transformed progenitor cells to produce a transgenic plant, wherein the polynucleotide sequence is expressed, and said transgenic plant exhibits an altered oil content phenotype relative to control plants.

The essential features of claims 1 and 6 is a nucleotide sequence encoding an ortholog of SEQ ID NO: 2.

The instant specification, however, only describes a nucleotide sequence (SEQ ID NO: 1) encoding the protein of SEQ ID NO: 2 having the property of increasing oil content when overexpressed in a plant. See in particular, pages 18-19, example 2; pages 26-30, example 5.

The specification does not describe structures that are orthologs of SEQ ID NO: 2. It may be emphasized that orthologs of SEQ ID NO: 2 would encompass structures having large and unspecified amino acid changes within the amino acid sequence of SEQ ID NO: 2. The specification does not describe function for said structures.

The specification does not describe the function of increasing seed oil content for said structures. The specification does not describe the function of increasing oil content in plants overexpressing said structures.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (increasing seed oil content) of SEQ ID NO: 2. An ortholog of SEQ ID NO: 2 would encompass a genus of proteins having helix-loop-helix DNA-binding domain. An ortholog of SEQ ID NO: 2 would also encompass any bHLH transcription factor protein. The state of art also describes that bHLH transcription factor are involved in activating stress-responsive genes. See for example, Smolen et al. (Genetics, 161:1235-1246, 2002; see in particular abstract). Thus, Applicant's broadly claimed genus encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 2.

The only species described in the specification is SEQ ID NO: 1, which encodes SEQ ID NO: 2. Structures (sequences) having large and unspecified changes in the amino acid sequence of SEQ ID NO: 2 are not described in the specification and thus their function is unknown.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6-8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000).

Alexandrov et al. disclose a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 65252 which has 100% sequence identity to instant SEQ ID NO: 2. The reference further discloses that the vector comprising said nucleic acid sequence is operably linked to a promoter which is inherently capable of causing

transcription in a plant cell (see pages 22-23, and 327-329), and wherein said promoter is either native or heterologous (non-native) to the nucleic acid sequence disclosed in the reference. The reference further discloses regenerating a transgenic plant from said transformed plant cell. The reference also discloses transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide disclosed in the reference. The reference further discloses that said transgenic plant is rapeseed or soybean. The reference also discloses producing transgenic seeds from said transgenic plant. See in particular, claims 1-34, pages 327- 335, 341-343, and SEQ ID NO: 65252.

Although Alexandrov et al. do not explicitly disclose increasing oil content in their transgenic plant, such a property would be inherent to the method of making a transgenic plant comprising over-expressing SEQ ID NO: SEQ ID NO: 65252 protein (100% identity with instant SEQ ID NO: 2, emphasis added) in Alexandrov et al. transgenic plant, unless the Applicant provides evidence to the contrary.

It is important to note that Alexandrov et al. method of making a transgenic plant is identical to the instantly claimed method of producing a high oil transgenic plant. All the active method steps required to practice the instantly claimed method are also disclosed by Alexandrov et al.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343,1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase “rich in glucosinolates” helps define the claimed invention, as evidenced by the specification and prosecution history, and

thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently “rich in glucosinolates”).

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

Likewise, instantly claimed transgenic plant is structurally identical to the transgenic plant of Alexandrov et al. The increased oil content characteristics is inherent to the expression of SEQ ID NO: 65252 (100% identity to instant SEQ ID NO: 2, emphasis added) polypeptide in Alexandrov et al. transgenic plant.

It may be emphasized that something which is old does not become patentable upon the discovery of a new property. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.

Accordingly, Alexandrov et al. anticipated the claimed invention.

9. Claims 1, 3-7, 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Jako et al. (Plant Physiol. 126:861-874, 2001, Applicant's IDS).

Jako et al. disclose a method of making a transgenic plant comprising transforming a plant (*Arabidopsis*) with a plant transformation vector which comprises a promoter operably linked a nucleotide sequence encoding a diacylglycerol acyltransferase. The overexpression of diacylglycerol acyltransferase in the transgenic plant resulted in increase in the seed oil content of said transgenic plant. The reference further discloses transgenic progeny obtained from said transgenic plant. The reference further discloses a method of recovering oil from said seed. See in particular, page 861, abstract; page 862, figure 1; page 863, figure 2; page 864, figures 3 and 4; page 865, figures 5-7; page 866, figures 8 and 9; page 867, table 1; pages 869-872, materials and methods.

It is important to note that this rejection is made because the recitation "ortholog" in claims 1 and 6 read on any polypeptide that has the property of increasing seed oil content when overexpressed in a plant.

Accordingly, Jako et al. anticipated the claimed invention.

10. Claims 1-9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Zou et al. (The Plant Cell, 9:909-923, 1997).

Zou et al. disclose a method of making a transgenic plant comprising transforming a plant (*Brassica napus*, rapeseed) with a plant transformation vector which comprises a promoter operably linked a nucleotide sequence encoding a *sn-2* Acyltransferase. The overexpression of *sn-2* Acyltransferase in the transgenic plant

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resulted in increase in the seed oil content of said transgenic plant. The reference further discloses transgenic progeny obtained from said transgenic plant. The reference further discloses a method of recovering oil from said seed. See in particular, page 909, abstract; page 910, table 1; page 912, table 2; page 913, table 3; page 914, figure 2; page 917, table 6; pages 919-921, materials and methods.

It is important to note that this rejection is made because the recitation "ortholog" in claims 1 and 6 read on any polypeptide that has the property of increasing seed oil content when overexpressed in a plant.

Accordingly, Zou et al. anticipated the claimed invention.

Conclusions

11. Claims 1-9 and 14 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VINOD KUMAR whose telephone number is (571)272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Vinod Kumar/

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